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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ARCHIE, NINA	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,353	KRIEG ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,29,31-33 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,29,31-33 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office is responsive to Applicant's amendment and response filed 7-14-09. Claims 28-29, 31-33, and 36 are currently pending and under examination.

Rejections Withdrawn

2. In view of the Applicant's amendment and remark following objections are withdrawn.

a) Claims 28-29, 31-33, and 36 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 19 and 21 of copending Application No. 10/956,745 in view of Oberhauser et al. 1992 Nucleic Acids Research vol 20 p. 533-538 and Hutcherson et al US 5,723,335 1998 (continuation of serial no 217,988, March 25, 1994), and Sonehara et al (J. Interferon and Cytokine Research, 1996, 16:799-803) has been withdrawn in view of Application No. 10/956,745 presently abandoned.

Claim Rejections Maintained - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. The rejection of claims 28-29, 31-33, and 36 under 35 U.S.C. 103(a) as being unpatentable over Kuramoto et al 1992 Jpn J. Cancer Res Vol. 83 pgs. 1128-1131 in view of Goodchild et al 1990 The American Chemical Society, Vol. 1, No. 3 pgs. 165-182, Hutcherson et al US Patent 5,723,335 March 3, 1998 (filed March 25, 1994), and Cheng et al US Patent No.

5,646,126 July 8, 1997 (filed February 28, 1994) is maintained for the reason set forth in the previous office action.

Applicant arguments:

Applicants arguments filed in response to the 35 U.S.C. 103(a), March 12, 2009 is carefully considered, but not found to be persuasive for the reasons below.

A) Applicants state the Examiner has dismissed Applicants arguments in regards to the unpredictability of phosphorothioate linkages with support from references Stein et al. (Science v. 261 p. 1004-1009, 1993) and Perez et al. (PNAS v. 21, p.5597-5561, 1994) (see Applicants Arguments filed 6/12/2008 pgs. 5-6) cited by Applicant. Applicants state the recited reference Stein et al. shows phosphorothioate modification can have unpredictable effects on an oligonucleotide (see Applicants Arguments filed 6/12/2008 pgs. 5-6). Furthermore, Applicants state recited reference Stein et al disclose phosphorothioate can unpredictably redirect oligonucleotide activity to create biological activity against targets where there previously was none and phosphorothioate modifications have many more biological effects than simply reducing oligonucleotide degradation in vivo (see Applicants Arguments filed 6/12/2008 pgs. 5-6). Applicants state the recited effects as set forth supra were not well understood and four possible explanations for the non-specific antisense effects of a particular phosphorothioate antisense oligonucleotide are described (see Stein et al 1993 Science v. 261 p. 1004-1009p. 1008, col. 3 and p. 1009, cols. 1 and 2). Applicants state additionally recited reference Perez et al. teaches that one should use caution when considering oligonucleotides with phosphorothioate backbones because of the danger of nuclear transcription factor induction.

Applicants argue the combination of references Kuramoto et al, Goodchild et al, Hutcherson, and Cheng et al of the rejection would only have hindsight reasoning. Applicants argue Hutcherson et al does not provide any teachings regarding inclusion of a palindrome within the sequence. Applicants state Hutcherson et al teach that phosphorothioate internucleotide linkage has immunostimulatory activity, thus Hutcherson et al describe molecules that are distinct from Kuramato et al and contain phosphorothioate modifications and do not require palindromes. Applicant argues in light of the known unpredictability of the phosphorothioate modifications it would not have been known at the time of the invention whether a phosphorothioate bond would substantially alter the shape of the oligonucleotide as to

totally destroy immunostimulatory activity, the teaching of Kuramato et al and Hutcherson et al would have different mechanisms.

B) Applicants argue the Declaration of Dr. Cy Stein was prepared in connection with an interference involving an application which derives priority from the same patent application to which the instant patent application claims priority US 08/386/063. Applicants argue the declaration is presented to the Office solely as evidence of the unpredictability of phosphate modifications in oligonuceotides. Applicants argue that the instant claims are irrelevant; as the objective of Dr. Cy Stein's Declaration was filed 3/12/2009 highlights the unpredictability of phosphate modifications on immunostimulation at the relevant time frame between the years of 1994-1996. Applicants state that it was not known that phosphorothioate backbones should be used with immunostimulatory oligonucleotides and that a change in backbone would affect the properties of the immunostimulatory oligonucleotides.

Examiner's Response to Arguments:

In response to Applicants statement in (A), in regards to Applicants argument of the unpredictability of phosphorothioate linkages with support from references Stein et al and Perez et al cited by Applicant is not found to be persuasive. The claims are drawn to an oligonucleotide, comprising: 5'-AACGTT-Y, 8-40 nucleotides in length, wherein each internucleotide linkage has a phosphate backbone modification, wherein the phosphate backbone modification is a phosphorothioate. Stein et al and Perez et al cited by Applicant both teach antisense oligodeoxynucleotides (oligos) (see abstract of Stein et al and Perez et al). Furthermore, Stein et al is teach antisense oligonucleotide with phosphorothioate as therapeutic agents and furthermore the antisense activity as inhibitors of viral replication (see abstract). Perez et al teach modified anaologues of antisense oligodeoxynucleotide with phosphorothioate used to inhibit gene expression (see abstract). Therefore the recited references drawn to antisense oligodeoxynucleotides are not commensurate in scope because the claims are not specifically limited to an antisense oligodeoxynucleotide and also because the recited references as set forth supra neither specifically teaches the oligonucleotide of the instant invention as claimed. Furthermore, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so

long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Moreover, in regards to unpredictable effects of phosphorothioate modifications and improper hindsight reasoning the following points are considered:

Point 1: Even though Applicants may present evidence showing there was not reasonably expectation of success, obviousness does not require absolute predictability; however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) (Claims directed to a method for the commercial scale production of polyesters in the presence of a solvent at superatmospheric pressure were rejected as obvious over a reference which taught the claimed method at atmospheric pressure in view of a reference which taught the claimed process except for the presence of a solvent. The court reversed, finding there was no reasonable expectation that a process combining the prior art steps could be successfully scaled up in view of unchallenged evidence showing that the prior art processes individually could not be commercially scaled up successfully.). See also *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1207-08, 18 USPQ2d 1016, 1022-23 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991) (In the context of a biotechnology case, testimony supported the conclusion that the references did not show that there was a reasonable expectation of success.); *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (The court held the claimed method would have been obvious over the prior art relied upon because one reference contained a detailed enabling methodology, a suggestion to modify the prior art to produce the claimed invention, and evidence suggesting the modification would be successful.) (see MPEP 2413.02).

Point 2: A rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395 (2007); *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); *Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152, 87 USPQ 303, 306 (1950) (See MPEP 2143.02)

Point 3: Obviousness requires only a reasonable expectation of success, the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (Claims directed to a method of treating depression with amitriptyline (or nontoxic salts thereof) were rejected as prima facie

obvious over prior art disclosures that amitriptyline is a compound known to possess psychotropic properties and that imipramine is a structurally similar psychotropic compound known to possess antidepressive properties, in view of prior art suggesting the aforementioned compounds would be expected to have similar activity because the structural difference between the compounds involves a known bioisosteric replacement and because a research paper comparing the pharmacological properties of these two compounds suggested clinical testing of amitriptyline as an antidepressant. The court sustained the rejection, finding that the teachings of the prior art provide a sufficient basis for a reasonable expectation of success.); Ex parte Blanc, 13 USPQ2d 1383 (Bd. Pat. App. & Inter. 1989) (Claims were directed to a process of sterilizing a polyolefinic composition with high-energy radiation in the presence of a phenolic polyester antioxidant to inhibit discoloration or degradation of the polyolefin. Appellant argued that it is unpredictable whether a particular antioxidant will solve the problem of discoloration or degradation. However, the Board found that because the prior art taught that appellant's preferred antioxidant is very efficient and provides better results compared with other prior art antioxidants, there would have been a reasonable expectation of success.) (See MPEP 2143.02)

Point 4: Predictability is determined at the time the invention was made whether an art is predictable or whether the proposed modification or combination of the prior art has a reasonable expectation of success is determined at the time the invention was made. *Ex parte Erlich*, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986) (Although an earlier case reversed a rejection because of unpredictability in the field of monoclonal antibodies, the court found "in this case at the time this invention was made, one of ordinary skill in the art would have been motivated to produce monoclonal antibodies specific for human fibroblast interferon using the method of [the prior art] with a reasonable expectation of success." 3 USPQ2d at 1016 (emphasis in original.) (See MPEP 2143.02)

Point 5: Kuramato et al is not drawn to an antisense oligodeoxynucleotide as taught in the recited references (Stein et al. and Perez et al.) of unpredictable effects cited by Applicant. However, Kuramato et al teach an oligonucleotide comprising a palindrome sequence as AACGTT as directed in the claim (see abstract). Although Kuramato does not specifically teach the use of phophorothioate phosphate backbone, Kuramato et al teach that the pharmacologic properties of the oligonucleotide are dependent on the oligonucleotide, not on method of synthesis. However, Hutcherson et al teach that phosphorothioate ODN analogs enhance immune stimulation. Thus, the skilled artisan would have modified the ODN disclosed by Kuramoto et al by adding phosphorothioate linkages based on the teachings a method of administering phosphorothioate oligonucleotide analogs which produce a localized immune stimulation and for enhancing the efficacy of anti-infective and anticancer agents (see abstract) as taught by Hutcherson et al. In reference to the unpredictability of the phosphorothioate modifications, based on the teachings of Goodchild et al, it would have been known at the time of the invention

to incorporate a phosphorothioate bond because Goodchild et al teach backbone modifications are utilized to improve the stability of the DNA to enzymatic degradation (see pg. 167 "Synthesis of Modified Oligonucleotides", pg. 175 "The Effect of Modification on Nuclease Resistance") thus discussing altering the shape of the oligonucleotide to enhance immunostimulatory activity, hence the teaching of Kuramato et al and Hutcherson et al would have immunostimulatory activity.

Therefore, for the reasons aforementioned above, the rejection does not include knowledge gleaned only from Applicant's disclosure and the motivation to combine references can be different than Applicants. Moreover, the prior art does not indicate absolute predictability and also the prior art explicitly discloses the advantages of recited modifications as set forth supra. Furthermore, given the use of oligonucleotides comprising phosphorothioate backbone modification to improve stability of the oligonucleotide as being well known in the art leading to predictable results and hence their use is obvious under KSR. KSR forcloses the argument that a specific teaching, suggestion, or motivation is required to support a finding obviousness. See the recent Board Decision Ex parte Smith, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007 (citing KSR, 82 USPQ2d at 1396) available at (http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).

Therefore the unpredictable effects of phosphate modification and improper hindsight reasoning are deemed unpersuasive.

In response to applicant's statement in (B), Dr. Cy Stein's statements filed 3/12/2009 as a Declaration is incorrect. It is noted that Dr. Cy Stein's statements in the instant application are submitted as an attachment which is a Declaration in another application prepared in connection with an interference involving an application which derives priority from the same patent application to which the instant patent application claims priority US 08/386/063. However Dr. Cy Stein's statements highlights the unpredictability of phosphate modifications on immunostimulation at the relevant time frame between the years of 1994-1996 and that it was not known that phosphorothioate backbones should be used with immunostimulatory oligonucleotides and that a change in backbone would affect the properties of the immunostimulatory oligonucleotides.

Consequently, for the reasons as set forth supra, the motivation to combine references can be different than Applicants. Moreover, the prior art does not indicate absolute predictability and also the prior art explicitly discloses the advantages of recited modifications as set forth supra. Furthermore, given the use of oligonucleotides comprising phosphorothioate backbone modification to improve stability of the oligonucleotide as being well known in the art leading to predictable results and hence their use is obvious under KSR. KSR forcloses the argument that a specific teaching, suggestion, or motivation is required to support a finding obviousness. See the recent Board Decision Ex parte Smith, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007 (citing KSR, 82 USPQ2d at 1396) available at (http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).

Therefore the Dr. Cy Stein's statements regarding unpredictability of phosphorothioate backbones modification with immunostimulatory oligonucleotides is deemed unpersuasive.

As outlined previously, the instant claims are drawn to an oligonucleotide, comprising: 5'-AACGTT-3', 8-40 nucleotides in length, wherein each internucleotide linkage has a phosphate backbone modification, wherein the phosphate backbone is a phosphorothioate (claim 28), comprising 5'-AACGTT-3', 8-40 nucleotides in length, and having at least one phosphate backbone modification, wherein the oligonucleotide is linked to a nucleic acid delivery complex (claim 29), wherein the oligonucleotide is covalently linked to the nucleic acid delivery complex (claim 31), wherein the nucleic acid delivery complex is a cationic lipid (claim 32), wherein the nucleic acid delivery complex is a sterol (claim 33); a composition comprising an oligonucleotide, comprising: 5'-AACGTT-3', 8-40 nucleotides in length, wherein each internucleotide linkage has a phosphate backbone modification, wherein the phosphate backbone is a phosphorothioate and a pharmaceutically acceptable carrier (claim 36).

Kuramato et al teach an oligonucleotide, comprising: 5'-AACGTT-3', 8-40 nucleotides in length.

Kuramoto et al teach that all oligonucleotide used were synthesized by the standard phosphoramidite method using an automatic DNA synthesizer.

Kuramato et al does not teach an oligonucleotide wherein internucleotide linkage has a phosphate backbone modification, wherein the phosphate backbone is a phosphorothioate, and having at least one phosphate backbone modification, wherein the oligonucleotide is linked to a

nucleic acid delivery complex, wherein the oligonucleotide is covalently linked to the nucleic acid delivery complex, wherein the nucleic acid delivery complex is a cationic lipid, wherein the nucleic acid delivery complex is sterol. Kuramoto et al does not teach a composition of comprising the oligonucleotide and a pharmaceutically acceptable carrier.

Goodchild et al teaches an oligonucleotide wherein the phosphate backbone modification is a phosphorothioate (see pg. 167 column 1 last paragraph, column 2 last paragraph). Goodchild et al teaches that backbone modifications are utilized to improve the stability of the DNA to enzymatic degradation (see pg. 167 "Synthesis of Modified Oligonucleotides", pg. 175 "The Effect of Modification on Nuclease Resistance"). Goodchild et al. teaches that shorter oligonucleotides are taken up more rapidly (see pg. 176 column 1 paragraph 5).

Hutcherson et al teach a composition (see column 5 lines 40-67, column 6 lines 31-43, column 7 lines 55-67, column 10 lines 46-57) comprising: an oligonucleotide delivery complex, wherein the oligonucleotide delivery complex contains an immunostimulatory CpG containing oligonucleotide associated (covalently) with a cationic lipid, wherein the CpG includes a phosphate backbone modification is a phosphorothioate (see abstract, column 5 lines 40-59, column 8 lines 31-50). Hutcherson et al teach a composition comprising a pharmaceutically acceptable carrier (see column 7 lines 49-55), wherein the oligonucleotide is synthetic (see column 8 lines 32-41).

Cheng et al teach oligonucleotides having phosphorothioate linkage covalently linked to a sterol.

It would have been prima facie obvious at the time the invention was made to modify the oligonucleotide of Kuramato et al by modifying the backbone and inclusion of linking the oligonucleotide in a delivery complex according to Hutcherson et al to because Hutcherson et al teaches that cationic lipids can significantly enhance the uptake and fate of oligonucleotides. It would also have been prima facie obvious to modify the backbone of the oligonucleotide of Kataoka et al to include phosphorothioate taught by Goodchild et al because Goodchild et al teaches that the backbone modifications prevent degradation by nucleases and increase or improve uptake (see section B pg. 167). It would have been prima facie obvious at the time the invention was made to modify the oligonucleotide of Kuramoto et al by inclusion of a sterol because both Cheng et al and Kuramato both teach oligonucleotide in a delivery complex.

Conclusion

4. No claims are allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov

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Nina A Archie

Examiner

GAU 1645

REM 3B31

/Robert A. Zeman/
for Nina Archie, Examiner of Art Unit 1645